

8-11-06 TFCW

1636/8



Attorney Docket No. 5470-451

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Margolis et al.
Application No.: 09/611,949
Filed: July 6, 2000
For: *HIV transcription repressor complex and compositions and methods based thereon*

Confirmation No. 6524
Group Art Unit: 1636
Examiner: D. Guzo

Date: August 10, 2006

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §1.97(c)**

Sir:

Attached is a list of documents on Form PTO-1449, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with the amendment by the U.S. Patent and Trademark Office to 37 C.F.R. § 1.98(a)(2)(ii) effective October 21, 2004.

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(c), before final Office Action or Allowance, whichever is earlier.

In accordance with the requirements of 37 C.F.R. § 1.97(c)(2), a check for the \$180.00 fee specified in 37 C.F.R. § 1.17(p) is enclosed. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.56 and Section 609 of the MPEP.

Respectfully submitted,

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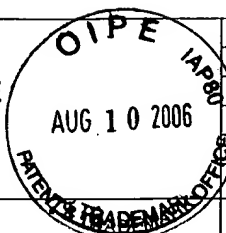
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U.S. PATENTS AND PATENT PUBLICATIONS					
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		

FOREIGN PATENT DOCUMENTS							
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OTHER NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	1.	Al Harthi et al. "Maximum suppression of HIV replication leads to the restoration of HIV-specific responses in early HIV disease" <i>AIDS</i> 14(7):761-770 (2000)	
	2.	Antoniou et al. "Severe Anemia Secondary to a Probable Drug Interaction between Zidovudine and Valproic Acid" <i>Clinical Infectious Diseases</i> 38:e38-40 (2004)	
	3.	Benkirane et al. "Activation of Integrated Provirus Requires Histone Acetyltransferase" <i>The Journal of Biological Chemistry</i> 273(38):24898-24905 (1998)	
	4.	Brooks et al. "Identification of T cell-signaling pathways that stimulate latent HIV in primary cells" <i>PNAS</i> 100(22):12955-12960 (2003)	
	5.	Brooks et al. "Molecular Characterization, Reactivation, and Depletion of Latent HIV" <i>Immunity</i> 19:413-423 (2003)	
	6.	Chun et al. "Effect of interleukin-2 on the pool of latently infected, resting CD4+ T cells in HIV-1-infected patients receiving highly active anti-retroviral therapy" <i>Nature Medicine</i> 5(6):651-655 (1999)	
	7.	Chun et al. "Presence of an inducible HIV-1 latent reservoir during highly active antiretroviral therapy" <i>Proc. Natl. Acad. Sci.</i> 94:13193-13197 (1997)	
	8.	Chun et al. "In vivo fate of HIV-1-infected T cells: quantitative analysis of the transition to stable latency" <i>Nature Med.</i> 387:183-188 (1997)	
	9.	Chun et al. "Quantification of latent tissue reservoirs and total body viral load in HIV-1 infection" <i>Nature</i> 387:183-188 (1997)	
	10.	Clotet et al. "Clinical management of treatment-experienced, HIV-infected patients with the fusion inhibitor enfuvirtide: consensus recommendations" <i>AIDS</i> 18(8):1137-1146 (2004)	
	11.	Cohen "Report of Novel Treatment Aimed at Latent HIV Raises the 'C Word'" <i>Science</i> 309:999-1000 (2005)	
	12.	Coombs et al. "Association between culturable human immunodeficiency virus type 1 (HIV-1) in semen and HIV-1 RNA levels in semen and blood: evidence for compartmentalization of HIV-1 between semen and blood" <i>J Infect Dis.</i> 177(2):320-330 (1998)	
	13.	Coull et al. "Targeted Derepression of the Human Immunodeficiency Virus Type 1 Long Terminal Repeat by Pyrrole-Imidazole Polyamides" <i>Journal of Virology</i> 76(23):12349-12354 (2002)	
	14.	Coull et al. "The Human Factors YY1 and LSF Repress the Human Immunodeficiency Virus Type 1 Long Terminal Repeat via Recruitment of Histone Deacetylase 1" <i>Journal of Virology</i> 74(15):6790-6799 (2000)	
	15.	Demonte et al. "Administration of HDAC inhibitors to reactivate HIV-1 expression in latent cellular reservoirs: implications for the development of therapeutic strategies" <i>Biochem Pharmacol.</i> 68(6):1231-1238 (2004)	
	16.	Di Mascio et al. "In a Subset of Subjects on Highly Active Antiretroviral Therapy, Human Immunodeficiency Virus Type 1 RNA in Plasma Decays from 50 to <5 Copies per Milliliter, with a Half-Life of 6 Months" <i>Journal of Virology</i> 77(3):2271-2275 (2003)	

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17.	Dornadula et al. "Residual HIV-1 RNA in Blood Plasma of Patients Taking Suppressive Highly Active Antiretroviral Therapy" <i>JAMA</i> 282(17):1627-1632 (1999)
18.	Dybul et al. "Pilot Study of the Effects of Intermittent Interleukin-2 on Human Immunodeficiency Virus (HIV)-Specific Immune Responses in Patients Treated during Recently Acquired HIV Infection" <i>The Journal of Infectious Diseases</i> 185:61-68 (2002)
19.	El Kharroubi et al. "Transcriptional Activation of the Integrated Chromatin-Associated Human Immunodeficiency Virus Type 1 Promoter" <i>Molecular and Cellular Biology</i> 18(5):2535-2544 (1998)
20.	Finzi et al. "Identification of a Reservoir for HIV-1 in Patients on Highly Active Antiretroviral Therapy" <i>Science</i> 278:1295-1300 (1997)
21.	Flamand et al. "Activation of CD8+ T lymphocytes through the T cell receptor turns on CD4 gene expression: Implications for HIV pathogenesis" <i>Proc. Natl. Acad. Sci.</i> 95:3111-3116 (1998)
22.	Fraser et al. "Reduction of the HIV-1-infected T-cell reservoir by immune activation treatment is dose-dependent and restricted by the potency of antiretroviral drugs" <i>AIDS</i> 14:659-669 (2000)
23.	Gunthard et al. "Evolution of Envelope Sequences of Human Immunodeficiency Virus Type 1 in Cellular Reservoirs in the Setting of Potent Antiviral Therapy" <i>Journal of Virology</i> 73(11):9404-9412 (1999)
24.	Hazuda et al. "Inhibitors of Strand Transfer That Prevent Integration and Inhibit HIV-1 Replication in Cells" <i>Science</i> 287:646-650 (2000)
25.	He et al. "The Regulation of HIV-1 Gene Expression: The Emerging Role of Chromatin" <i>DNA and Cell Biology</i> 21(10):697-705 (2002)
26.	He et al. "Counterregulation of Chromatin Deacetylation and Histone Deacetylase Occupancy at the Integrated Promoter of Human Immunodeficiency Virus Type 1 (HIV-1) by the HIV-1 Repressor YY1 and HIV-1 Activator Tat" <i>Molecular and Cellular Biology</i> 22(9):2965-2973 (2002)
27.	Hsia et al. "Chromatin Disruption and Histone Acetylation in Regulation of the Human Immunodeficiency Virus Type 1 Long Terminal Repeat by Thyroid Hormone Receptor" <i>Molecular and Cellular Biology</i> 22(12):4043-4052 (2002)
28.	Jennings et al. "An Improved Culture Method for Stimulating the Production of HIV from PBMCs" 10 th Conference on Retroviruses and Opportunistic Infections, Abstract No. 672 (2003)
29.	Jennings et al. "The use of valproic acid in HIV-positive patients" <i>Ann Pharmacother.</i> 34(11):1113-1116 (1999)
30.	Jordan et al. "The site of HIV-1 integration in the human genome determines basal transcriptional activity and response to Tat transactivation" <i>The EMBO Journal</i> 20(7):1726-1738 (2001)
31.	Jordan et al. "HIV reproducibly establishes a latent infection after acute infection of T cells <i>in vitro</i> " <i>The EMBO Journal</i> 22(8):1868-1877 (2003)
32.	Kulkosky et al. "Prostratin: activation of latent HIV-1 expression suggests a potential inductive adjuvant therapy for HAART" <i>Blood</i> 98(10):3006-3015 (2001)
33.	Kutsch et al. "Direct and Quantitative Single-Cell Analysis of Human Immunodeficiency Virus Type 1 Reactivation from Latency" <i>Journal of Virology</i> 76(17):8776-8786 (2002)
34.	Lertora et al. "Pharmacokinetic interaction between zidovudine and valproic acid in patients infected with human immunodeficiency virus" <i>Clin Pharmacol Ther.</i> 56(3):272-278 (1994)
35.	Maggi et al. "The Effect of Divalproex Sodium on Viral Load: A Retrospective Review of HIV-Positive Patients With Manic Syndromes" <i>Can J Psychiatry</i> 46:359-362 (2001)
36.	Margolis et al. "Human Transcription Factor YY1 Represses Human Immunodeficiency Virus Type 1 Transcription and Virion Production" <i>Journal of Virology</i> 68(2):905-910 (1994)
37.	Moog et al. "Sodium valproate, an anticonvulsant drug, stimulates human immunodeficiency virus type 1 replication independently of glutathione levels" <i>J Gen Virol.</i> 77(Pt 9):1993-1999 (1996)
38.	Moriuchi et al. "USF/c-Myc Enhances, While Yin-Yang 1 Suppresses, the Promoter Activity of CXCR4, a Coreceptor for HIV-1 Entry" <i>The Journal of Virology</i> 162:5986-5992 (1999)
39.	Myers et al. "Dilution Assay Statistics" <i>Journal of Clinical Microbiology</i> 32(3):732-739 (1994)
40.	Natarajan et al. "HIV-1 replication in patients with undetectable plasma virus receiving HAART" <i>The Lancet</i> 353:119-120 (1999)
41.	Palmer et al. "New Real-Time Reverse Transcriptase-Initiated PCR Assay Copy Sensitivity for Human Immunodeficiency Virus Type 1 RNA in Plasma" <i>J. Clin Microbiol</i> 41(10):4531-4536 (1996)
42.	Pazin et al. "NF-kappa B-mediated chromatin reconfiguration and transcriptional activation of the HIV-1 enhancer <i>in vitro</i> " <i>Genes Dev.</i> 10(1):37-49 (2003)

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43.	Phiel et al. "Histone Deacetylase Is a Direct Target of Valproic Acid, a Potent Anticonvulsant, Mood Stabilizer, and Teratogen" <i>The Journal of Biological Chemistry</i> 276(39):36734-36741 (2001)	
44.	Pierson et al. "Reservoirs for HIV-1: Mechanisms for Viral Persistence in the Presence of Antiviral Immune Responses and Antiretroviral Therapy" <i>Annu. Rev. Immunol.</i> 18:665-708 (2000)	
45.	Pomerantz et al. "Reservoirs, Sanctuaries, and Residual Disease: The Hiding Spots of HIV-1" <i>HIV Clin Trials</i> 4(2):137-143 (2003)	
46.	Prins et al. "Immuno-activation with anti-CD3 and recombinant human IL-2 in HIV-1-infected patients on potent antiretroviral therapy" <i>AIDS</i> 13:2405-2410 (1999)	
47.	Quivy et al. "Synergistic Activation of Human Immunodeficiency Virus Type 1 Promoter Activity by NF-kB and Inhibitors of Deacetylases: Potential Perspectives for the Development of Therapeutic Strategies" <i>Journal of Virology</i> 76(21):11091-11103 (2002)	
48.	Ramratnam et al. "Intensification of Antiretroviral Therapy Accelerates the Decay of the HIV-1 Latent Reservoir and Decreases, But Does Not Eliminate, Ongoing Virus Replication" <i>J. Acquir Immune Defic Syndr</i> 35(1):33-37 (2004)	
49.	Ramratnam et al. "The decay of the latent reservoir of replication-competent HIV-1 is inversely correlated with the extent of residual viral replication during prolonged anti-retroviral therapy" <i>Nature Medicine</i> 6(1):82-85 (2000)	
50.	Reinberg "New HIV Therapy Clears Out Hidden Virus" www. healthfinder.gov (August 11, 2005)	
51.	Romerio et al. "Repression of Human Immunodeficiency Virus Type 1 through the Novel Cooperation of Human Factors YY1 and LSF" <i>Journal of Virology</i> 71(12):9375-9382 (1997)	
52.	Shen et al. "Resting CD4+ T Lymphocytes but Not Thymocytes Provide a Latent Viral Reservoir in a Simian Immunodeficiency Virus-Macaca-nemestrina Model of Human Immunodeficiency Virus Type 1-Infected Patients on Highly Active Antiretroviral Therapy" <i>Journal of Virology</i> 77(8):4938-4949 (2003)	
53.	Sheridan et al. "Histone acetyltransferases regulate HIV-1 enhancer activity in vitro" <i>Genes and Dev.</i> 11:3327-3340 (1997)	
54.	Siliciano et al. "Long-term follow-up studies confirm the stability of the latent reservoir for HIV-1 in resting CD4+ T cells" <i>Nature Medicine</i> 9(6):727-728 (2003)	
55.	Siliciano et al. "Latency and viral persistence in HIV-1 infection" <i>The Journal of Clinical Investigation</i> 106(7):823 (2000)	
56.	Siliciano et al. "A long-term latent reservoir for HIV-1: discovery and clinical implications" <i>Journal of Antimicrobial Chemotherapy</i> 54:6-9 (2004)	
57.	Smith et al. "Valproic acid and HIV-1 latency: beyond the sound bite" <i>Retrovirology</i> 2:56 (2005)	
58.	Stellbrink et al. "Effects of interleukin-2 plus highly active antiretroviral therapy on HIV-1 replication and proviral DNA (COSMIC trial)" <i>AIDS</i> 16:1479-1487 (2002)	
59.	Strain et al. "Heterogeneous clearance rates of long-lived lymphocytes infected with HIV: Intrinsic stability predicts lifelong persistence" <i>PNAS</i> 100(8):4819-4824 (2003)	
60.	Strain et al. "Effect of Treatment, during Primary Infection, on Establishment and Clearance of Cellular Reservoirs of HIV-1" <i>JID</i> 191:1410-1418 (2005)	
61.	Van Lint et al. "The expression of a small fraction of cellular genes is changed in response to histone hyperacetylation" <i>Gene Expr.</i> 5(4-5):245-253 (1996)	
62.	Van Lint et al. "Transcriptional activator and chromatin remodeling of the HIV-1 promoter in response to histone acetylation" <i>The EMBO Journal</i> 15(5):1112-1120 (1996)	
63.	Van Praag et al. "OKT3 and IL-2 Treatment of Purging of the Latent HIV-1 Reservoir in Vivo Results in Selective Long-Lasting CD4+ T Cell Depletion" <i>Journal of Clinical Immunology</i> 21(3):218-226 (2001)	
64.	Verdin et al. "Chromatin disruption in the promoter of human immunodeficiency virus type 1 during transcriptional activation" <i>The EMBO Journal</i> 12(8):3249-3259 (1993)	
65.	Wang et al. "IL-7 is a potent and proviral strain-specific inducer of latent HIV-1 cellular reservoirs of infected individuals on virally suppressive HAART" <i>The Journal of Clinical Investigation</i> 115(1):128-137 (2005)	
66.	Winslow et al. "HIV-1 latency due to the site of proviral integration" <i>Virology</i> 196(2):849-854 (1993)	
67.	Witvrouw et al. "Cell type-dependent effect of sodium valproate on human immunodeficiency virus type 1 replication in vitro" <i>AIDS Res Hum Retroviruses</i> 13(2):187-192 (1997)	

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	68.	Wong et al. "Recovery of Replication-Competent HIV Despite Prolonged Suppression of Plasma Viremia" <i>Science</i> 278:1291-1295 (1997)	
	69.	Ylisastigui et al. "Polyamides Reveal a Role for Repression in Latency within Resting T Cells of HIV-Infected Donors" <i>JID</i> 190:1429-1437 (2004)	
	70.	Ylisastigui et al. "Coaxing HIV-1 from resting CD4 T cells: histone deacetylase inhibition allows latent viral expression" <i>AIDS</i> 18:1101-1108 (2004)	
	71.	Ylisastigui et al. "Mitogen-Activated Protein Kinases Regulate LSF Occupancy at the Human Immunodeficiency Virus Type 1 Promoter" <i>Journal of Virology</i> 79(10):5952-5962 (2005)	
	72.	Zhang et al. "Quantifying Residual HIV-1 Replication in Patients Receiving Combination Antiretroviral Therapy" <i>The New England Journal of Medicine</i> 340(21):1605-1613 (1999)	

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